Maryland Board of Pharmacy Public Board Meeting

Agenda Date: October 21, 2015

Name	Title	Present	Absent	Present	Absent
Board Committee					
Ashby, D.	Commissioner				
Bouyoukas, E	Commissioner				
Gavgani, M. Z.	Commissioner/President				
Jones, David H.	Commissioner/Secretary				
Peters, Roderick	Commissioner				
Robinson, T.	Commissioner				
Rochester, C.	Commissioner				
Roy, S.	Commissioner				
Smith, J.	Commissioner/Treasurer				
St. Cyr, II, Z. W.	Commissioner				
Yankellow, E.	Commissioner				
Zagnit, B.	Commissioner				
Board Counsel					
Bethman, L.	Board Counsel				
Felter, B.	Staff Attorney				
Board Staff					
Naesea, L.	Executive Director				
Wu, Y.	Compliance Manager				
-	Licensing Manager				
Waddell, L.	Acting Administration and Public Support Manager				
Jeffers, A.	Legislation/Regulations Manager				
Johnson, J.	MIS Manager				

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	A.) M. Gavgani, Board President	Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.	
Report (s)	B.) D. Jones, Secretary	 Call to Order Sign-in Introduction and of meeting attendees – (Please indicate on sign-in sheet if you are requesting CE Units for attendance) Distribution of Agenda and packet materials Review and approve Previous Month's Minutes 	
II. A. Executive Director Report	L. Naesea, Executive Director	1. Operations Updates 2. Meetings Update	
B. Administration and Public Support (APS)	L. Waddell, APS Manager	1. Personnel Updates 2. Contracts and Procurement	
C. MIS	J. Johnson, MIS Manager	1. MIS Update	
D. Licensing	Y. Wu, Compliance Manager	1. Unit Updates 2. Monthly Statistics License Type New Renewed Reinstated Total Distributor 20 97 0 1015	

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Subject	Responsible Party		D	iscussion			Action Due Date (Assigned To)
						1	
		Pharmacy	14	0	0	2058	
		Pharmacist	109	432	0	10905	
		Vaccination	92	36	0	4064	
		Pharmacy Intern - Graduates	2	0	0	11	
		Pharmacy Intern - Students	37	0	0	185	
		Pharmacy Technician	89	332	9	9190	
		Student Technician	0	0	1	973	
E. Compliance	Y. Wu, Compliance Manager	1. Unit Upd					
F. Legislation & Regul ations	A. Jeffers, Legislation & Regulations Manager	REGULATIONS 10.34.09 Fees This chapter was rechapter clean up.		uant to the Go	overnor's ini	tiative and	

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		Proposal submitted September 17 th for DHMH sign-off and publication. The anticipated publication date is October 16 th .	
		10.34.10.10 Pharmacist, Pharmacy Intern and Pharmacy Technician Code of Conduct The chapter was revised pursuant to Board recommendation.	
		Proposal submitted September 23 rd for DHMH sign-off and publication. The anticipated publication date is November 13th.	
		10.34.19 Sterile Pharmaceutical Compounding This chapter was revised pursuant to 2015 Legislation.	
		Proposal submitted on September 2 nd , for DHMH sign-off and publication. The anticipated publication date is November 13th.	
		10.34.29 Drug Therapy Management This chapter was revised pursuant to 2015 Legislation brought by the Maryland Pharmacy Coalition.	
		Proposal submitted on September 25 th for DHMH sign-off and publication. The anticipated publication date is November 13th.	
		10.34.33 Prescription Drug Repository Program This chapter was revised pursuant to Federal law and regulations.	
		Released for informal comment August 21 st – Sept. 16 th .	
		DRAFT Proposal COMAR 10.34.33 RxDrugRep 101515	
		Informal Comments and Approval of Board Response:	
		Dental Bd comment 10.34.33	

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		Don Taylor - Drug Repository Regs Informal comment	
		MedStar - informal comment 090915	
		NACDS comment 10.34.33	
		OHCQ comment COMAR 10.34.33 Repository Regs 082415	
		Vet AG Comment 10.34.33	
		DRAFT Bd Resp-Informal Comments 10.34.33	
		10.34.39 Pharmacist Administration of Self-Administered Drugs This chapter was revised pursuant to 2015 Legislation brought by the Maryland Pharmacy Coalition.	
		Returned to September Practice Committee for further consideration.	
		DRAFT II Self-Administered Drugs - 10.34.39 for Bd App 101515	
		Informal Comment and Approval of Revised Board Response and Revised Proposal:	
		Don Taylor - 10.34.39	
		Jill McCormack NACDS	
		MPC Rx proposed draft regs comment AUG 2015	

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		REVISED DRAFT Bd Resp-Informal Comments 10.34.39 Self-Administered drugs	
		REGULATORY REVIEW AND EVALUATION ACT	
		10.13.08.01	
		.01 Identification of Purchaser, and Record of Sale.	
		The sale of needles and syringes or other paraphernalia shall be made by the pharmacist only in good faith to patients showing proper identification and indication of need.	
		Board approval requested for the Practice Committee recommendation of no revisions to this regulation and that COMAR 10.13.08.01 continues to be effective.	
		LEGISLATION:	
		Pain Management Bill - FYI – The Practice Committee recommended no position and that position was sent to OGA on Sept. 23 rd .	
		OTHER MATTERS:	
		1) Revisions to USP 797 Sterile Pharmaceutical Compounding	
		usp-gc-797-proposed-revisions-sep-2015	
		Board approval requested to delegate the review and	

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III. Committee Reports A. Practice Committee	D. Jones, Chair	comments for the USP 797 revisions to the Practice Committee. 2) FDA Invitation: Inter-Governmental Meetings on Pharmacy Compounding and Drug Supply Chain Security- November 2015 Linda Bethman attending. Inquiries: Randy Trumbule, The Pharmacare Network AMS - expiration dates Draft Bd Response – AMS expiration dates	
B. Licensing Committee	J. Smith, Chair	 Review of Pharmacist Applications: Review of Pharmacy Intern Applications: P. Kerolus – Applicant is requesting if Intern registration be obtained by a foreign grad using FPGEE and Oral comp (without taking TOEFL) Licensing Committee's recommendation: Inform applicant that Board's regulations states that an applicant must have a certificate to establish education equivalency (i.e.: FPGEC). Review of Pharmacy Technician Applications: 	
		 4. Review of Distributor Applications: a. Wasatch Rx, LLC – Applicant is requesting 	

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		waiver of SAWD accreditation. Facility will be shipping legend drugs only (ie: OTC and noncontrolled) and products will be sold over the phone and shipped directly via FedEx. <u>Licensing Committee's recommendation:</u> Deny request to waive VAWD.	
		 a. Ethical Factor Rx, LLC (Moosic, PA) - Specialty pharmacy wishing to dispense to one patient in Maryland. MD Licensed pharmacist to be part time 20 hours per week and dispense to this on MD patient. Licensing Committee's recommendation: Approve for licensure and must provide a list of MD patients upon renewal. SAJAL ROY RECUSED 	
		 6. Review of Pharmacy Technicians Training Programs: 7. New Business: a. Pharmacy Intern Applications — Application states that foreign grad applicants needs to provide educational equivalency and an oral competency exam approved by the Board per the regulations. Many callers have called arguing that this statement does not prohibit them from being able to take the Berlitz Oral Comp in lieu of the 	
		TOEFL. Should the verbiage of the application be changed? <u>Licensing Committee's recommendation:</u> To	

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		replace "Must provide a copy of your original Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate" With "These requirements could be met with a copy of your original Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate" b. Review of Resident Pharmacy Application c. Review of Waiver Pharmacy Application d. Review of Non-Resident Pharmacy Application e. Pharmacy Technician Program Survey Questions - Licensing Committee's recommendation: To reach out to the following programs to pilot the survey: • Anne Arundel Community College (ASHP Accredited program) • MedStar Health (Hospital based program) • University of Maryland (hospital based program) • University of Maryland (hospital based program as a backup) • Rite-Aid Corporation (Retail/Chain based program) • Community College of Baltimore County (Board of Pharmacy approved program)	
C. Public Relations Committee	B. Zagnit, Chair	Public Relations Committee Update:	
D. Disciplinary	T. Robinson, Chair	Disciplinary Committee Update 1. Review of Opening Inspection Form for Sterile Compounding Facilities.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
E. Emergency Preparedness Task Force	S. Roy, Chair	Emergency Preparedness Task Force Update	
IV. Other Business & FYI	M. Gavgani, President		
V. Adjournment	M. Gavgani, President	The Public Meeting was adjourned at At P.M. M. Gavgani convened a Closed Public Session to conduct a medical review of technician applications.	
		C. The Closed Public Session was adjourned at P.M. Immediately thereafter, M. Gavgani convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.	